

# **TECHNICAL DOSSIER OF BIOCIDE**

## **CLEAN MAX PROTECT**

The technical dossier has been prepared in accordance with the requirements of Annex № 2 to Art. 3, para. 1 of the Ordinance on the form and content of the documents required for issuing a permit for placing on the market of a biocide or a group of biocides under Art. 18 of the Law for protection against the harmful effects of chemical substances and mixtures CMD № 8 / 22.01.2018.  
(SG No. 9 / 26.01.2018).

**2020**

**I. Details of the person placing the biocidal product on the market and the manufacturer of the biocidal product and the active substance.**

**1. Name, address and telephone number of the entity, which releases the biocide on the market**

**„Diva 691“ Ltd**

35 Varshava Street, Plovdiv

Phone: +359 888 992 064; +359 888 148 221

e-mail: [dvproduct691@gmail.com](mailto:dvproduct691@gmail.com)

**2. Name and address of the manufacturer of the biocidal product and address of the manufacturing plant.**

**„Diva 691“ Ltd**

35 Varshava Street, Plovdiv

Phone: +359 888 992 064; +359 888 148 221

e-mail: [dvproduct691@gmail.com](mailto:dvproduct691@gmail.com)

**3. Name and address of the manufacturer of the active substance (s) and address of the manufacturing plant: *Ethanol (ethyl alcohol)***

**Manufacturer and supplier of the active substance: (1st supplier)**

**„ZAHARNI ZAVODI“ AD**

Gorna Oryahovitsa, 5100

Str. “St. Knyaz Boris I “№ 29

Bulgaria

Тел. 0618/69-500; факс: 0618/2 17 09

e-мeйл: [office@zaharnizavodi.com](mailto:office@zaharnizavodi.com)

[ethanol@zaharnizavodi.com](mailto:ethanol@zaharnizavodi.com)

The supplier ZAHARNI ZAVODI AD is included in the list under Art. 95 of Regulation (EU) No 528/2012 for the active substance ethanol for product types 1, 2 and 4.

**Trade name:** Ethanol (ethyl alcohol) of agricultural origin (80-100%), denatured by a general method according to PPZADS, with methyl ethyl ketone, isopropyl alcohol and denatonium benzoate (bitrex).

The active substance contains ethanol 96.50% (v / v), isopropyl alcohol 1 l / 100 l, methyl ethyl ketone 1 l / 100 l and denatonium benzoate 1 g / 100 l. Does not contain methanol (attached certificate of analysis – **Annex № 1**).

## **Manufacturer and supplier of the active substance: (2nd supplier)**

**„VP BRANDS INTERNATIONAL“ AD,  
owner of ESENTIKA alcohol factory, Plovdiv**  
Dunav bul. № 5,  
4003 Plovdiv, North region  
Bulgaria  
Tel.: 359 (0)32 606 916 /+359 (0)32 306 783  
e-mail: office@vp-brands.com  
office@essentica.eu

The supplier VP BRANDS INTERNATIONAL AD is included in the list under Art. 95 of Regulation (EU) No 528/2012 for the active substance ethanol for product types 1, 2 and 4.

**Trade name:** Ethanol denatured with isopropanol, methyl ethyl ketone and denatonium benzoate (bitrex).

The active substance contains ethanol 96.54% v / v, isopropyl alcohol 1 l / 100 l, methyl ethyl ketone 1 l / 100 l and denatonium benzoate 1 g / 100 l. Does not contain methanol (attached certificate of analysis - Annex № 1).

### **Annex № 1:**

- Documents of Zaharni zavodi AD:
  - ECHA decision on the inclusion in the list of active substances and suppliers referred to in Article 95 (1) of REGULATION (EU) № 528/2012
  - Declaration from an approved supplier for compliance with Art. 95 (1) of Regulation 528/2012 on the placing on the market and use of biocidal products.
  - Certificate of analysis.
- Documents of VP BRANDS INTERNATIONAL AD:
  - ECHA decision to include in the list of active substances and suppliers referred to in Article 95 (1) of REGULATION (EU) № 528/2012
  - Declaration from an approved supplier for compliance with Art. 95 (1) of Regulation 528/2012 on the placing on the market and use of biocidal products.
  - Certificate of analysis.

### **Annex № 2:**

- Safety data sheet of "ZAHARNI ZAVODI" AD for Ethanol (ethyl alcohol) of agricultural origin (80-100%), denatured by a common method according to PPZADS, with methyl ethyl ketone, isopropyl alcohol and denatonium benzoate (bitrex);

- Safety data sheet of VP BRANDS INTERNATIONAL AD for Ethanol, denatured with Isopropanol, Methyl ethyl ketone and Denatonium benzoate (Bitrex).

## II. Biocidal identity.

### 1. Trade name of the biocidal product and production code where appropriate.

**CLEAN MAX PROTECT**

### 2. Detailed quantitative and qualitative data on the composition of the biocidal product:

Chemical name	CAS №/ EC №	SDS with trade name	Contents (% w/w)	Classification
Ethanol (Annex № 2)	64-17-5/ 200-578- 6	1. Ethanol (ethyl alcohol) of agricultural origin (80-100%), denatured by the general method according to PPZADS, with methyl ethyl ketone, isopropyl alcohol and denatonium benzoate (bitrex)	80 %	According to table 3.1. of Annex VI to Regulation (EC) (1272/2008 (CLP) Flam. Liq. 2; H225 The manufacturer also classifies ethanol as: Eye Irrit. 2; H319; STOT SE 3; H336  (see SDS of Zaharni Zavodi and VP Brands International AD - Appendix № 2).
Isopropyl alcohol (Appendix № 2)	67-63-0/ 200-661- 2	Ethanol (ethyl alcohol) of agricultural origin (80-100%), denatured by the general method according to PPZADS, with methyl ethyl ketone, isopropyl alcohol and denatonium benzoate (bitrex)	≤ 1 %	Flam. Liq. 2 Eye Irrit. 2 STOT SE 3 H225 H319 H336
Methyl ethyl ketone (Appendix № 2)	76-93-3/ 201-159- 0	Ethanol (ethyl alcohol) of agricultural origin (80-100%), denatured by the general method according to	≤ 1 %	Flam. Liq. 2 Eye Irrit. 2 STOT SE 3 H225 H319 H336 EUH066

		PPZADS, with methyl ethyl ketone, isopropyl alcohol and denatonium benzoate (bitrex)		
Hydrogen peroxide (Annex № 3)	7722-84-1	Hydrogen Peroxide 50% Oxypure	0,12 %	Skin Corr. 1A H314 Ox. Liq. 1 H271 Acute Tox. 4 H302 Acute Tox. 4 H332
Deionized water	7732-18-5 231-791-2	Deionized water	До 100 %	Not classified

## 2.1. Information on the active substance: ETHANOL

### 2.1.1. Trade name:

Ethanol denatured with isopropanol, methyl ethyl ketone and denatonium benzoate (bitrex).

### 2.1.2. Identifier of the active substance according to art. 18 (2) of Regulation (EC)№ 1272/2008 (CLP)

Table № 1

<b>IUPAC name</b>	Ethanol
<b>CAS №</b>	64-17-5
<b>EC №</b>	200-578-6
<b>Index №</b>	603-002-00-5
<b>REACH registration №</b>	01-2119457610-43-XXXX

### 2.1.3. Concentration in metric units in the composition of the biocidal product.

**80 g/100 g (80 % w/w)**

The active substance is included in Annex II to Commission Delegated Regulation (EU) № 1062/2014 of 4 August 2014 concerning the work program for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) № 528 / 2012 of the European Parliament and of the Council.

### MAIN GROUP 1: Disinfectants:

- **Product type 1.** *Human hygiene,*
- **Product type 2.** *Disinfectants and algaecides not intended for direct use on humans or animals,*
- **Product type 4.** *Area of use related to food and feed,*

In accordance with Regulation (EU) № 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products.

#### **2.1.4. Efficacy and resistance to the target organisms and field of application:**

##### **2.1.4.1. Efficacy (see Annex № 5):**

- a) spectrum of action: bactericidal, including tuberculocidal, yeasticidal, fungicidal, virucidal (enveloped viruses);
- b) organisms subject to the proposed use: bacteria (including mycobacteria), yeasts, fungi and (enveloped) viruses;
- c) products, organisms or objects to be protected: food and drink, pets;
- d) effects on organisms which are the subject of the proposed use and recommended concentrations for the use of the active substance:
  - has bactericidal (incl. tuberculocidal), virucidal (enveloped viruses), yeasticidal and fungicidal action.
  - recommended concentrations: 68 - 80%.
- e) mode of action, including exposure time:
  - the specific mode of action of alcohols is little known.

It is generally believed that on the basis of increased efficiency in the presence of water, alcohols lead to destruction of the cell membrane and rapid denaturation of proteins, with consequences for cellular metabolism and cell lysis. This is supported by evidence of dehydrogenase denaturation in *Escherichia coli* and increased lag phase in *Enterobacter aerogenes*, which could be due to inhibition of the metabolism required for rapid cell division.

Exposure time: 30 seconds - 1 minute.

##### **2.1.4.2. Information on identified cases or possibility of developing resistance and appropriate measures to prevent development when data are available:**

There are insufficient data on the selective acquisition of resistance to the active substance regardless of its long-term use.

##### **2.1.4.3. Intended field of application and category of users:**

The field of application is: disinfection of instruments used in human medicine and small areas in industry, public sector and household.

Consumer category: professional use.

## 2.1.5. Summary of physico-chemical, toxicological and ecotoxicological data for the active substance related to the classification of the active substance as dangerous; hazard category (s), pictograms, hazard statements

### 2.1.5.1. Physico-chemical, toxicological and ecotoxicological data related to the classification of the active substance as dangerous according to Regulation (EC) № 1272/2008 (CLP).

#### Physico-chemical data

Source: ECHA

<https://echa.europa.eu/bg/brief-profile/-/briefprofile/100.000.526>

Table № 2

Indicators	Source ECHA
Type	Liquid, very mobile, colorless
Smell	Characteristic of alcohol
Flash point at 101 325 Pa	12.85°C
Melting / freezing point at 101 325 Pa	-114.15°C
Partial coefficient Log Kow	-0.35 (20°C)
Boiling point at 101 325 Pa	78.29°C
Vapor pressure	57.26 hPa (19.65°C)
Dynamic at 20°C	1.2 mPa.s
Density	0.786 g/cm <sup>3</sup> (25°C)
Solubility in water	789 g/L (20°C)
Flammability	Highly flammable (100%)

#### Toxicological data

Source: ECHA

<https://echa.europa.eu/bg/brief-profile/-/briefprofile/100.000.526>

#### Acute toxicity

## **Orally**

LD50 1 187 - 15 010 mg/kg bw (rats)

LD50 7 800 - 22 500 mL/kg bw (rats)

LD50 8 300 mg/kg bw (mice)

## **Inhalatory:**

LC50 (6 h) 82.1 - 92.6 mg/L air (rats)

LC50 (4 h) 115.9 - 133.8 mg/L air (rats)

LC50 (60 min) 60 000 ppm (mice)

## **Irritation/ corrosivity**

Skin: No harmful effects are observed (not irritating)

Eyes: Adverse effects are observed (irritation)

## **Sensitization**

Skin sensitization

No adverse effects observed (not sensitizer)

Respiratory sensitization

No adverse effects (no sensitizer)

## **Repeated dose toxicity**

Orally

NOAEL (mice): 9 700 mg/kg bw/day

NOAEL (mice): 9 400 mg/kg bw (total dose)

Inhalatory

NOAEC (rats): 6.66 mg/L въздух

NOAEC (mice): 1.3 mg/L въздух

NOEC (rats): 130 mg/m<sup>3</sup> въздух

NOEC (mice): 130 mg/m<sup>3</sup> въздух

## **Neurotoxicity**

Inhalation route: Adverse effects have been observed with NOAEC 19,000 mg / m<sup>3</sup> (subchronic, rats)

## **Immunotoxicity**

Inhalation route: No adverse effects were observed with NOAEC 40 000 mg / m<sup>3</sup> (subchronic, rats)

**Genotoxicity:** no data available;

**Carcinogenesis:** no carcinogenic effect

**Teratogenesis:** no data available.



## **Ecotoxicological data**

### **Source ECHA**

<https://echa.europa.eu/bg/brief-profile/-/briefprofile/100.000.526>

### **Biodegradability in water - easily biodegradable (100%)**

**Bioaccumulation:** the substance has a low potential for bioaccumulation. Bioconcentration factor (BCF): 3.2 and bioaccumulation is not expected.

### **Ecotoxicity:**

#### **Acute (short-term) toxicity to fish**

LC50 for freshwater fish - 11.2 g/L

#### **Chronic aquatic toxicity to fish**

EC10 / LC10 or NOEC for freshwater fish - 250 mg/L

#### **Acute (short-term) toxicity to aquatic invertebrates**

EC50 / LC50 for freshwater invertebrates - 5.012 g/L

EC50 / LC50 for marine invertebrates - 857 mg/L

#### **Chronic aquatic toxicity to invertebrates**

EC10 / LC10 or NOEC for freshwater invertebrates - 9.6 mg/L

EC10 / LC10 or NOEC for marine invertebrates - 79 mg/L

#### **Toxicity to algae**

EC50 / LC50 for freshwater algae - 275 mg/L

EC50 / LC50 for seaweed - 1.9 g/L

EC10 / LC10 or NOEC for freshwater algae - 11.5 mg/L

EC10 / LC10 or NOEC for seaweed - 1.58 g/L

### **2.1.5.2. Physico-chemical, toxicological and ecotoxicological data that lead to specific requirements and / or restrictions on use (e.g. in persons at risk, with significant skin resorption, etc.)**

**Chemical stability:** stable under recommended conditions of use, transport and storage. Reacts with strong oxidants and strong acids.

**Reactivity:** no dangerous reactions are known under the recommended conditions of storage and use of the product. If not stored and used as directed, vapors may form explosive mixtures with air at room temperature.

**Conditions to avoid:** heat, flames, sparks and ignition sources.

**Materials to avoid:** violent reaction is possible with oxidants, alkali metals, alkaline earth metals, strong acids and strong bases, metals, peroxides, metal salts, halogens, flammable materials.

**Possibility of dangerous reactions:** reacts with strong oxidants and strong acids!

**Incompatible materials:** are not known under recommended storage and use conditions. Reducing substances; aluminum metals, at high temperatures; strong mineral acids; oxidants.

**Hazardous decomposition products:** does not decompose if stored and used as intended! During a fire or thermal decomposition, carbon dioxide is released (CO<sub>2</sub>).

#### **2.1.6. Classification of the active substance according to Regulation 1272/2008.**

The active substance is included in Table 3.1. of Annex № VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labeling and packaging of substances and mixtures, amending and repealing Directives 67/548 / EEC and 1999/45 / EC and amending Regulation (EC) № 1907/2006.

**The active substance has a harmonized classification.**

- Flammable liquids, category 2, H225.

**The supplier Zaharni Zavodi AD has proposed an additional classification:**

- Serious eye damage / eye irritation, category 2, H319
- Specific target organ toxicity, single exposure, category 3, H336

(see SDS – Annex № 2).

**Labeling:**

**Pictograms:**



GHS02



GHS07

**Signal word:** Dangerous

**Hazard warnings**

H225: Highly flammable liquid and vapor.

H319: Causes serious eye irritation.

H336: May cause drowsiness or dizziness.

**Safety recommendations:**

P210 Protect from heat / sparks / open flame / hot surfaces. No smoking!

P233 Keep the vessel (container) tightly closed!

P240 Grounding / equipotential bonding of the vessel and the receiving device!

P241 Use explosion-proof electrical / ventilating / lighting / equipment!

P242 Use only non-sparking tools!

P243 Take precautions against the release of static electricity!

P280 Wear protective gloves / protective clothing / safety goggles / face shield!

P303+P361+P353 IF ON SKIN (OR HAIR): Take off immediately all contaminated clothing. Rinse skin with water / shower!

P264 Wash thoroughly after use!

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Keep rinsing.

P337+P313 in case of prolonged eye irritation: get medical help or seek medical advice!

P370+P378 In case of fire: Use for extinction: alcohol-resistant foam, dry powder or water jet!

P403+P235 Store in a well-ventilated place. Store in a cool place!

P501 Dispose of contents / container in accordance with regulations!

**2.2. Data for each of the other chemicals included in the biocidal product:**

<b>Chemical name</b>	<b>CAS №/ EC №</b>	<b>SDS with trade name</b>	<b>Contents (% w/w)</b>	<b>Classification</b>
Hydrogen peroxide (Appendix № 3)	7722-84-1	Hydrogen Peroxide 50% Oxypure	0,12 %	Skin Corr. 1A H314 Ox. Liq. 1 H271 Acute Tox. 4 H302 Acute Tox. 4 H332

Deionized water	7732-18-5 231-791-2	Deionized water	До 100 %	Not classified
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The inclusion of Hydrogen Peroxide in the composition of the biocidal product does not lead to a change in the classification of the product due to its low concentration of 0.12%, according to the specified specific concentration limits.:

**Specific concentration limits (Regulation (EU) No 1272/2008 (CLP)):**

- Skin Corr. 1A; H314:  $C \geq 70 \%$
- Skin Corr. 1B; H314:  $50 \% \leq C < 70 \%$
- Skin Irrit. 2; H315:  $35 \% \leq C < 50 \%$
- Ox. Liq. 1; H271:  $C \geq 70 \%$
- Ox. Liq. 2; H272:  $50 \% \leq C < 70 \%$
- STOT SE 3; H335:  $C \geq 35 \%$
- Eye Dam. 1; H318:  $8 \% \leq C < 50 \%$
- Eye Irrit. 2; H319:  $5 \% \leq C < 8 \%$

**Annex № 3**

Safety data sheet of Hydrogen Peroxide.

**III. Physical and chemical properties of the biocidal product:**

<b>Appearance:</b>	Течност, с лек опалесцент (по еталон)
<b>Color:</b>	Transparent (by standard)
<b>Smell:</b>	Slight alcoholic odor (by standard)
<b>pH (undiluted at 20°C):</b>	5,50-7,0
<b>Melting / freezing point (°C):</b>	No data
<b>Boiling point / interval:</b>	No data
<b>Flash point:</b>	12.85°C (Ethanol)
<b>Auto-ignition temperature</b>	No data
<b>Decomposition temperature</b>	No data
<b>Evaporation rate:</b>	No data
<b>Flammability (solid, gas):</b>	Flammable liquid
<b>Lower / upper explosion limit</b>	No data
<b>Vapor pressure</b>	No data
<b>Vapor density</b>	No data
<b>Relative density</b>	0,8720 - 0,8740
<b>Solubility</b>	Unlimited in water Dissolves well in acetone, benzene, methyl alcohol

<b>Partition coefficient: n-octanol / water</b>	No data
<b>Viscosity</b>	No data
<b>Oxidizing properties</b>	No data
<b>Explosive properties</b>	Ethanol forms vapors / mixed with air can explode.

**1. Storage stability, shelf life. Influence of light, temperature and humidity on the technical characteristics of the biocidal product. Reactivity with respect to the material of which the packaging is made.**

Stable under recommended storage and use conditions.

Stability is determined by observing the specific product and on the basis of the experience gained from observations of similar products in real conditions.

Taking into account the data from the stability tests, the specified minimum shelf life is 36 months from the date of manufacture. The stability of the product is also guaranteed by the storage conditions. Packages should be stored tightly closed in a dry and ventilated place at a temperature of 5 ° to 25 ° C, away from sources of heat and direct sunlight..

**Regarding the physico-chemical properties the product is classified as highly flammable, category 2, H 225,** in accordance with Regulation 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labeling and packaging of substances and mixtures, amending and repealing Directives 67/548 / EEC and 1999/45 / EC and amending Regulation (EC) No 1907/2006.

**2. Technical characteristics of the biocidal product (e.g. foaming, wettability and dusting).**

Non-foaming liquid product.

**3. Physical and chemical compatibility with other products including co-administered biocidal products.**

**Chemical stability:** Stable under the recommended conditions of use, transport and storage (protected from sunlight, in a cool place, separate from incompatible substances - strong oxidants and strong acids). Shelf life: 3 years.

**Reactivity:** no dangerous reactions are known under the recommended conditions of storage and use of the product. If not stored and used as directed, vapors may form explosive mixtures with air at room temperature.

**Conditions to avoid:** high temperatures (over 25<sup>0</sup>C), flames, sparks and ignition sources, direct sunlight, frost.

**Materials to avoid:** violent reaction is possible with oxidants, alkali metals, alkaline earth metals, strong acids and strong bases, metals, peroxides, metal salts, halogens, flammable materials.

**Dangerous reactions:** are not known under the recommended storage and use conditions.

**Hazardous decomposition products:** does not decompose if stored and used as intended! During a fire or thermal decomposition, carbon dioxide is released (CO<sub>2</sub>).

#### **IV. Analytical methods for determining the concentration of the active substances in the biocidal product (Annex № 4).**

##### **Analytical method for determining the concentration of alcohols in the biocidal product.**

The alcohol content is determined by capillary gas chromatography with a flame ionization detector. Butan-2-ol is used as an internal standard.

##### *Equipment*

Gas chromatograph

Flame ionization detector

Quartz capillary column 30 m long and 0.32 mm internal diameter coated with poly [(cyanopropyl) (phenyl)] [dimethyl] siloxane (film thickness) 1.8 µm).

Gas chromatographic software, computer and printer

##### *Test solutions*

(a): Tested preparation

(b) Internal standard test solution: Dilute 1.0 ml of butan-2-ol to 50.0 ml with test solution (a). Dilute 5.0 ml of this solution to 100.0 ml with test solution (a).

(c) Comparison solution: Dilute 0.5 ml of butan-2-ol, 0.5 ml of propan-1-ol and 0.5 ml of propan-2-ol to 50.0 ml with water.

##### **Way of working**

The chromatographic procedure can be carried out as follows:

- carrier gas helium or nitrogen, flow division 1: 5 and linear velocity 35 cm / s;
- temperature regime: column 40°C - 12 min / 100°C / min to 240°C / holding 10 min.

injector: 280°C

detector: 280°C

Inject 1 µl of reference solution (c). The sensitivity of the system is adjusted so that the height of the alcohol peaks is not less than 50% of the scale of the recorder.

Inject 1 µl of test solution (b). The areas of the ethanol peaks are determined in the obtained chromatogram.

The calculation of the results is performed by the method of the internal standard.

- The relative correction factor for the substance is determined RCF:

$$RCF(i) = \frac{\frac{AREA(i)}{MASS(i)}}{\frac{AREA(in\ cm)}{MASS(in\ cm)}}$$

where:

Area (i) = the area of the peak of the i-th determined component of the analyzed mixture;

Mass (i) - the mass of the sample of the analyzed mixture to which the quantity of internal standard has been added;

Area (in cm) - the peak area of the internal standard;

Mass (i) - the mass of the added internal standard;

- The amount of the determined substance (i) is calculated by the formula:

$$G(i) = \frac{AREA(i) \times MASS(in\ cm)}{MASS(i) \times RCF(i)}$$

## **V. Type of biocidal product and areas of application:**

### **1. Type of the biocide:**

Clear liquid, with a slight opalescent standard.

### **2. Type of biocidal product / group of biocidal products, according to Annex V to Regulation (EU) № 528/2012.**

**Main group 1.** Disinfectants.

**Product type 2.** Disinfectants and algaecides not intended for direct use on humans or animals.

**Product type 4.** Area of use related to food and feed.

### **3. Spectrum of action**

Bactericidal, incl. mycobactericidal and tuberculocidal; yeasticidal, fungicidal

and virucidal limited (enveloped viruses).

#### **4. Field of application:**

Liquid ready-to-use biocide for disinfection of instruments used in human medicine, as well as on small areas in the food and industrial field, in the household and public sector (food, cosmetics, health and medical institutions, dental and veterinary practices , social homes, fitness and SPA salons, hairdressing salons, massage and beauty salons, commercial sites, offices, etc.).

#### **5. Organisms that are the subject of the proposed use:**

Bacteria, including mycobacteria, yeasts, fungi, enveloped viruses.

#### **6. Products, organisms or objects that need to be protected, where available:**

Food for humans and animals, drinks, pets.

#### **7. Consumer category: *professional and mass.***

### **VI. Efficacy and resistance to test report data and / or literature data, where applicable.**

#### **1. Biological efficacy data, taking into account proposed areas of application and uses, including geographical and climatic conditions.**

##### **Efficacy data:**

##### **Bactericidal action:**

Protocol № 145 / 02.07.2020 - Laboratory for Disinfection, Sterilization and Bioindicators at NCIPD (Annex № 5):

##### **Examination method:**

BDS EN 14561: 2006: Chemical disinfectants and antiseptics. Quantitative carrier test to evaluate the bactericidal action of instruments in human medicine. Test method and requirements (phase 2, step 2).

##### **Tested test strains:**

Staphylococcus aureus ATCC 6538

Enterococcus hirae ATCC 10541

Pseudomonas aeruginosa ATCC 15442

##### **Conclusion:**

According to the requirements of BDS EN 14561: 2006 for evaluation of products intended for disinfection of instruments used in human medicine, the test sample



from the disinfectant "CLEAN MAX PROTECT" achieves bactericidal activity ( $\lg R \geq 5$ ) activity when applied as a ready for use product (without dilution) at exposure time of 3 minutes and under the following conditions: 20°C and presence of additional load for clean conditions - 0.3 g / l bovine albumin.

**Fungicide and yeasticidal action:**

Protocol № 146 / 02.07.2020 - Laboratory for Disinfection, Sterilization and Bioindicators at NCIPD (Annex № 5):

**Examination method:**

BDS EN 14562: 2006: Chemical disinfectants and antiseptics. Quantitative test with a vehicle for the evaluation of fungicidal or drajcidic action in instruments used in human medicine. Test method and requirements (phase 2, step 2).

**Tested test strains:**

Candida albicans ATCC 10231

Aspergillus brasiliensis ATCC 16404 (spores - "prickly" conidiospores  $\geq 75$  %).

**Conclusion:**

According to the requirements of BDS EN 14562: 2006 for evaluation of products intended for disinfection of instruments used in human medicine, the test sample from the disinfectant "CLEAN MAX PROTECT" achieves fungicidal ( $\lg R \geq 4$ ) activity when applied as a ready-to-use product (without dilution) at an exposure time of 3 minutes and under the following conditions: 20°C and the presence of an additional load for clean conditions - 0.3 g / l bovine albumin.

**Bactericidal and / or fungicidal action:**

Protocol № 147 / 02.07.2020 - Laboratory for Disinfection, Sterilization and Bioindicators at NCIPD (Annex № 5):

**Examination method:**

BDS EN 13697: 2015 + A1: 2019: Chemical disinfectants and antiseptics. Quantitative testing on a non - porous surface to evaluate the bactericidal and / or fungicidal action of chemical disinfectants and antiseptics used in the food and industrial field, in the household and in the public sector. Method for testing without machining and requirements (phase 2, step 2).

**Tested test strains:**

Staphylococcus aureus ATCC 6538

Escherichia coli ATCC 10536

Enterococcus hirae ATCC 10541

Pseudomonas aeruginosa ATCC 15442

Candida albicans ATCC 10231

Aspergillus brasiliensis ATCC 16404 (spores - "prickly" conidiospores  $\geq 75$  %)

**Conclusion:**

According to the requirements of BDS EN 13697: 2015 + A1: 2019 for an evaluation of bactericidal and yeasticidal / fungicidal action of a product intended for disinfection of non-porous surfaces, the tested sample of the disinfectant "CLEAN MAX PROTECT" achieves bactericidal ( $\lg R \geq 4$ ) and fungicidal ( $\lg R \geq 3$ ) activity when administered as a ready-to-use product (without dilution) at an exposure time of 2 minutes and under the following conditions: 20 ° C and additional load for pure conditions - 0.3 g / 1 bovine albumin.

#### **Annex № 5.**

**Efficacy data** – protocols and literature data on the efficacy of the biocide.

- Persistence of coronaviruses on inanimate surfaces and their inactivation with biocidal agents, G. Kampf\*, Journal of Hospital Infection 104 (2020) 246-251.
- Effectiveness of disinfection with alcohol 70% (w/v) of contaminated surfaces not previously cleaned, Maurício Uchikawa Graziano, 2013 Mar.-Apr.; 21(2):618-23.
- Interim guidance for environmental cleaning in non -healthcare facilities exposed to SARS -CoV-2, ECDC Technical report, 18 February 2020.
- Efficacy of ethanol against viruses in hand disinfection, G. Kampf\*, Journal of Hospital Infection 98 (2018) 331-338.

**Mode of action and time of impact:** the specific mode of action of alcohols is little known. It is generally believed that on the basis of increased efficiency in the presence of water, the alcohols lead to destruction of the cell membrane and rapid denaturation of proteins, with consequences for cellular metabolism and cell lysis. This is supported by evidence of denaturation of dehydrogenases in *Escherichia coli* and increased lag phase in *Enterobacter aerogenes*, which could be due to inhibition of metabolism required for rapid cell division..

#### **2. Resistance data, if available.**

There are no data on established cases of resistance or on the possibility of developing resistance.

### **VII. How to use. Exposure time**

#### **1. A description of the method of use, including a description of the application systems, if any.**

The product is ready for use and is applied undiluted.  
Instruments used in human medicine are treated for 3 minutes.

The surfaces are treated for 2 minutes, until completely wet. No subsequent washing is performed. Do not use on delicate surfaces sensitive to alcohol (e.g. acrylic glass).

**Important:** Do not use for disinfection of large surfaces (over 2 m<sup>2</sup>) due to the flammability of the biocide. Do not use near ignition sources or appliances, which are plugged into the electrical network!

## **2. Concentration of working solution and consumption rate.**

The biocide is ready for use and is applied undiluted.

## **3. Number and duration of treatments and, if necessary, additional information on specific geographical and climatic requirements:**

The product is applied as often as necessary, observing the recommended exposure time and according to the disinfection practice..

## **4. Final concentration of the biocidal product and of the active substance in the treated article, if necessary (e.g. water in cooling or heating systems, surface water)**

Not applicable.

## **5. The time interval to be observed between:**

(a) the individual applications of the biocidal product - no interval is required

b) the application of the biocidal product and the use of the treated products - no interval is required.

c) the use of the biocidal product and the access of people or animals to the treated areas, indicating the means and measures for disposal, the time for ventilation of these areas, instructions for cleaning the equipment - no interval is required.

## **6. Precautions for use, transport and storage as means of collective and personal protection, fire-fighting measures, covering of furniture or equipment, disposal of foodstuffs for humans and / or animals, instructions for prevention of exposure of animals.**

### **6.1. Handling of the substance / product**

#### **For professional use:**

Only store the quantities necessary for the normal course of the work process at the workplace; do not leave containers / packages / containers open; to be used in

well-ventilated rooms. Avoid contact with eyes, inhalation of vapors / aerosols. Take off contaminated clothing immediately. Do not eat, drink or smoke while working. Wash hands before breaks and after work. Take off work clothes immediately after work. Wear chemically resistant gloves (EN 374) / protective clothing / safety goggles with side protection (EN 166) / face mask.

Used only with adequate ventilation. Store in tightly closed original container. Follow the instructions for safe work.

Work in accordance with the rules of industrial hygiene and safety. Keep away from drains, surface waters and groundwater. Do not mix with other products.

Keep away from flames and hot surfaces. Protect from heat and direct sunlight.

### **In mass use:**

There are no special requirements for the recommended conditions of use.

## **6.2. Storage**

The product should be stored in tightly closed original packaging, in dry and ventilated rooms at a temperature of 5 ° to 25 ° C, away from heat sources and direct sunlight.

Properly stored, the biocide has a shelf life of 3 years.

Materials to avoid - reacts with strong oxidants and strong acids!

To comply with the requirements of the Ordinance on the procedure and manner of storage of hazardous chemical substances and mixtures.

## **6.3. Firefighting measures**

### **Suitable fire extinguishing media**

Depending on the burning material. Dry powder. A jet of water aerosol. Extinguish larger fires with water jet or alcohol-resistant foam.

**Means unsuitable for fire fighting for security reasons** – not recommended: dense water jet, inert gases, halons.

### **Specific hazards associated with exposure to the substance / product, combustion products, gases**

As a result of combustion or thermal decomposition, hazardous products can be released: carbon dioxide, carbon monoxide. Exposure to products resulting from burns or thermal decomposition can be dangerous to health.

**Special protective equipment for firefighters:** In case of fire or thermal decomposition, carbon dioxide (CO<sub>2</sub>) is released. Wear self-contained breathing apparatus and suitable protective clothing, incl. gloves and face / eye protection.

## 6.4. Occupational exposure control

Limit values in the air at the workplace, according to Ordinance № 13 for protection of workers from risks related to exposure to chemical agents at work:

Chemical agent	CAS №	8 hours	15 minutes
Ethyl alcohol	64-17-5	1000 mg/m <sup>3</sup>	-
Isopropyl alcohol	67-63-6	980.0 mg/m <sup>3</sup>	1225.0 mg/m <sup>3</sup>
Methyl ethyl ketone	78-93-3	590 mg/m <sup>3</sup>	885 mg/m <sup>3</sup>

### For professional use:

**Respiratory protection:** There are no special requirements under the recommended conditions of use. Avoid inhalation of vapors / aerosols using protective face mask.

**Hand protection:** chemically resistant gloves (EN 374)

**Eye protection:** safety goggles with side protection (EN 166).

**Skin protection:** appropriate protective clothing and footwear.

**Environmental exposure control:** do not allow to enter drains, surface or ground water, or soil. In case of an accident and / or accident to notify the relevant control bodies - RIEW.

### In mass use:

There are no special requirements for the recommended conditions of use.

## 6.5. Measures in case of accidents and incidents

### Personal precautions

Take measures to ensure the supply of fresh air indoors. Switch off all sources of ignition and ventilate the entire area.

The work in the affected area is terminated, the affected area is limited and marked; only workers, repair or other activities to eliminate the accident or incident are allowed in the area, and their number is limited to the required minimum. Absorbed with liquid binders (sand, diatomaceous earth, universal binders). Workers in case of accidents should wear appropriate work clothes, shoes and personal protective equipment - gloves / protective clothing / goggles / face mask.

### 6.6. Environmental protection measures and cleaning agents

Do not allow pollution of the environment. Do not allow to enter drains, surface or ground water, or soil. In case of accident and / or spillage of the product, take measures for its localization and limitation. Limit spillage when using inert

absorbent materials (eg sand, earth, diatomaceous earth); to collect and place the spilled quantity in a container for temporary storage, after which it shall be handed over to persons holding a permit by the order of art. 67 of the WMA. In case of discharge into surface and groundwater, soil, wastewater, drainage systems to notify the control authority - RIEW.

Expired biocide and residues thereof, as well as its packaging are treated in compliance with the requirements of the Waste Management Act.

## **7. First aid measures, including antidotes, if known.**

### **Description of first aid measures**

General advice: Show the label and / or safety data sheet at admission to the doctor.

**When inhaled:** the victim should be moved to fresh air immediately. If symptoms persist, seek qualified medical attention.

**In case of skin contact:** wash immediately with drinking water. Remove contaminated work clothing immediately. If symptoms of skin irritation (e.g. redness) occur and persist, seek medical attention.

**In case of eye contact:** remove contact lenses, if any, and as far as possible. Immediately flush eyes with plenty of running water with the eyelids open for at least 15 minutes and seek medical advice..

**In case of swallowing:** do not induce vomiting, but if the head happens to be kept upright. Rinse mouth and throat with water as they may have been affected by ingestion. Seek medical attention immediately and show the package or label.

**Treatment:** the treatment is specialized.

**Protection of first aiders:** to use personal protective equipment.

## **8. Procedures for waste management of biocidal mixtures and their packaging.**

The waste from the biocide as residual quantities and packages to be collected temporarily in special tightly closing and marked containers, after which to be handed over to persons, holding a permit by the order of art. 67 of the Waste Management Act.

Waste code (determined by the respective operator):

Wastes from manufacture, formulation, supply and use of greases, lubricants, soaps, laundry and cleaning mixtures, disinfectants and cosmetics.

Code 07 06 01 \* wash water and mother liquor.

Code 15 01 10 \* packages containing residues of dangerous substances or contaminated with dangerous substances.

**9. Data on specific environmental hazards, including undesirable or unintended side effects, for example, on beneficial or other non-target organisms.**

No data available.

**10. Data for each repellent or preservative contained in the biocidal product intended to prevent adverse effects on non-target organisms (where available).**

Not applicable.

**11. Transport of a product containing ethanol and quaternary ammonium compound:**

**Land transport, Sea transport (IMDG), Air transport (ICAO-TI / IATA-DGR**

UN number: 1170

The exact name of the shipment: ethanol solution

Hazard class (es): 3

Label (s): 3

Packing group: II

Dangerous for the environment: No.

Marine pollutant: No.

Special precautions for user: None known.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC

Code: The product is not transported in bulk tankers.

**Other important information:**

ADR

Classification code: F1

Tunnel restriction code: D / E

Hazard identification number: 33

IMO / IMDG

EmS: F-E, S-D

The product is classified, labeled and packaged in accordance with the requirements of ADR and the provisions of the IMDG Code

Transport includes special provisions for certain classes of dangerous substances packaged in limited quantities.

**According to physico-chemical properties the product is classified as highly flammable, category 2, H 225 Highly flammable liquids and vapors, in accordance with Regulation 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labeling and packaging of substances and mixtures, amending and repealing Directives 67/548 / EEC and 1999/45 / EC and amending of Regulation (EC) № 1907/2006**

## **VIII. Toxicological and ecotoxicological data on the biocidal product**

### **1. Toxicological and ecotoxicological data related to the classification of the biocidal product as hazardous.**

#### **Toxicological data:**

No test data on the mixture.

Details of the active substance in the mixture - see data above.

#### **Additional toxicological information** – none.

According to the presented SDS of ethyl alcohol, the biocidal product is classified as:

Serious eye damage / eye irritation, cat. 2, H319

Specific target organ toxicity, single exposure, category 3, H336.

#### **Ecotoxicological data**

No test data on the mixture.

Details of the active substance in the mixture - see data above.

In terms of ecotoxicological properties, the biocidal product is not classified as dangerous for the aquatic environment in accordance with Regulation (EC) № 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labeling and packaging of substances and mixtures, repealing Directives 67/548 / EEC and 1999/45 / EC and amending Regulation (EC)№ 1907/2006 (CLP).

### **2. Toxicological and ecotoxicological data that lead to specific requirements and / or restrictions on use (eg in persons at risk, in case of significant skin resorption, etc.):**

No data

## **IX. Product classification**

Flam. Liq 2/ Flammable liquid. Category 2, H225.

Eye Irrit. 2/ Serious eye irritation, Category 2, H319.

STOT SE 3/ Specific target organ toxicity, single exposure, Category 3, H336.

**Labeling:**

**Pictograms:**





**GHS02**



**GHS07**

**Signal word:** Dangerous

**Danger warnings:**

**H 225** Highly flammable liquid and vapors.

**H 319** Causes serious eye irritation.

**H 336** May cause drowsiness or dizziness.

**Safety recommendations:**

**P102** Keep out of the reach of children

**P210** Keep away from heat / sparks / open flames / hot surfaces. No smoking.

**P233** Keep container tightly closed.

**P241** Use explosion-proof electrical / ventilating / lighting /.../ equipment.

**P242** Use only non-sparking tools.

**P243** Take precautionary measures against static discharges.

**P244** Store only in the original package.

**P305 + P351 + P338** IN CASE OF EYE CONTACT: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Keep rinsing.

**P370 + P378** In case of fire: Use ABC powder extinguisher to extinguish.

**P403 + P235** Store in a well-ventilated place. Keep cool.

**P501** Dispose of contents / container in accordance with regulations.

Product vapors may form explosive mixtures with air.

Do not use for disinfection of large surfaces (over 2 m<sup>2</sup>) due to the flammability of the biocide.

Consumer category: Professional and mass.

## **X. Biocide packaging data**

### **1. Material, type, shape**

The product is packaged in plastic packages with different capacities. The packages are closed with sprayer caps and transport caps (PP).

#### **Packaging for mass use:**

Polyethylene terephthalate (PET) with a capacity of 1 L.

**Packaging for professional use:**

Polypropylene (PP) with a capacity of 5 L

Polypropylene (PP) with a capacity of 10 L

Polypropylene (PP) with a capacity of 20 L

Acrylonitrile butadiene styrene (ABS) CUB with capacity 1 000 L

**2. Compatibility of the material with the biocidal product**

Interaction with the packaging material - the biocidal product does not interact with the packaging material.

The tests for compatibility of the commercial packaging with the final product at room temperature, refrigerator, thermostat and light, show no deviations from the standard analytical specification.

**Tactile hazard warnings and devices that make the package inaccessible to children:**

Packages for general use must be provided with tactile hazard statements.

**3. Capacity (mass or volume).**

See p. 1.

**XI. Draft label - Annex № 6****XII. Product Safety Data Sheet - Annex № 7.**